



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3608]

Stephen Kalinoski: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarment Stephen Kalinoski from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Kalinoski was convicted of a felony for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Kalinoski was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Kalinoski failed to respond. Mr. Kalinoski's failure to request a hearing within the prescribed timeframe constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit applications for special termination of debarment to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and

Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, debarments@fda.hhs.gov, or 240-402-8743.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On July 14, 2017, Mr. Kalinoski entered a plea of guilty to one count of conspiracy to commit wire fraud, a felony offense, in violation of 18 U.S.C. 371, and on December 19, 2017, judgment was entered against Mr. Kalinoski in the U. S. District Court for the Eastern District of New York.

The factual basis for this conviction is as follows: Mr. Kalinoski was the director of pharmacy and registered pharmacist in charge at Med Prep Consulting, Inc. (Med Prep), a medical drug repackager located and incorporated in New Jersey in 1994. Med Prep manufactured, repackaged, processed, packed, labeled, held, compounded, and distributed various drug products, including pain management medications, anesthesia and operating room drugs, and oncology and dialysis drugs. Mr. Kalinoski worked at Med Prep from approximately 2003 to its closing in the summer of 2013 and was in charge of repackaging and compounding operations and other drug-processing activities.

Between approximately January 2007 and April 2013, Mr. Kalinoski knowingly and intentionally conspired with other individuals to devise a scheme and artifice to defraud healthcare providers and to obtain money and property from them by means of materially false and fraudulent pretenses, representations, and promises, and for the purpose of executing such

scheme and artifice, and attempting to do so, to transmit and cause to be transmitted, by means of wire communication in interstate commerce, writings, signs, signals, pictures, and sounds.

Specifically, during this time period, Mr. Kalinoski conspired with others to introduce and introduced, or caused the introduction of, adulterated and misbranded drugs into interstate commerce, all with the intent to defraud and mislead healthcare providers. The adulterated drugs Mr. Kalinoski introduced or caused to be introduced into interstate commerce were adulterated because they were prepared, packed, and held under insanitary conditions and because the drugs consisted in whole or in part of a filthy, putrid, and decomposed substance. The misbranded drugs Mr. Kalinoski introduced or caused to be introduced in interstate commerce were misbranded because the drugs were dangerous to health when used as labeled and because the labeling on the drugs regarding use by dates and the strength of the ingredients were false and misleading. Mr. Kalinoski assured healthcare providers that they were receiving drug products from Med Prep that were produced in full compliance with the law, were compounded and packaged in compliance with chapter 797 of the United States Pharmacopeia (USP 797) and would be safe for patients. Mr. Kalinoski also told healthcare providers that the beyond use dates that Mr. Kalinoski assigned to sterile drug products were supported by sterility testing that satisfied the requirements of USP 797. These representations were made in, among other places, quarterly reports that were sent by email to healthcare providers and on Med Prep's website. Mr. Kalinoski did not inform healthcare providers of failures to comply with USP 797 and basic sterility practices, and breaches of aseptic technique in Med Prep's cleanroom, which occurred repeatedly at Med Prep's facility.

By engaging in this conduct, Mr. Kalinoski violated Federal and State law applicable to drug preparation and created serious risks for patients who were being treated for cancer and

other illnesses. Mr. Kalinoski misrepresented the quality of Med Prep's drug processing and repackaging operation to increase market share, and he engaged in substandard practices to save money and increase his profits. Relying on these misrepresentations and omissions, healthcare providers paid Med Prep approximately \$34,970,881 for its services between approximately 2007 and 2012.

Based on his conviction, FDA sent Mr. Kalinoski by certified mail on September 27, 2019, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Kalinoski was convicted, as set forth in section 306(l)(1) of the FD&C Act, of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Kalinoski an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to file a timely request for a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Kalinoski received the proposal on October 3, 2019. Mr. Kalinoski did not request a hearing and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(b) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Stephen Kalinoski has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Stephen Kalinoski is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), applicable (see DATES) (see sections 201(dd) and 306(c)(1)(B) and (c)(2)(A)(ii) of the FD&C Act (21 U.S.C. 321(dd) and 335a(c)(1)(B) and (c)(2)(A)(ii)). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Stephen Kalinoski during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Kalinoski provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications from Mr. Kalinoski during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Kalinoski for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2019-N-3608 and sent to the Dockets Management Staff (see ADDRESSES). All such submissions are to be filed in one copy. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 13, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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